K090754 P81 of 94

[redacted]

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 2 1 2011

As required by section 807.92(c)

5.1 GENERAL INFORMATION

Trade Name	LIPOCONTROL
Classification Name	LASER INSTRUMENT, SURGICAL, POWERED
Class	II
Product Code	ORK
CFR section	878.4810
Device panel	General & Plastic Surgery
Legally marketed predicate devices	PHARAON LIPO manufactured by OSYRIS MEDICAL and cleared as K073617 SMARTLIPO MPX laser with SMARTSENSE manufactured by CYNOSURE and cleared as K083379 GE logic E9, manufactured by GE Healthcare and cleared as K082185 CTG 2000sa, manufactured by ULTRAGUIDE and cleared as K022354
Submitter	OSYRIS Medical 60, avenue Halley 59650 VILLENEUVE D'ASCQ FRANCE
Contacts	Pr JAOUAD ZEMMOURI CEO jaouad.zemmouri@osyris.com Phone ; +33 (0)3 20 67 90 00 Fax: +33 (0)3 20 04 46 24 Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) idrubaix@nordnet.fr

5.2 Device Description

The medical device LIPOCONTROL is based on the use of a laser module allowing the emission of a beam of coherent light at 970nm ±10nm at a maximum power of 25W. The laser module consists of laser diodes assembled in series and optically aligned in order to focus in an optical fibre of 200µm or more. The optical fibre is screwed onto the SMA 905 connector of the laser module.

LipoControl contains a localisation system. This localisation system is based on a magnetic sensor (LipoBird), positioned on the handpiece and a field transmitter. With this localization system, an informative function and a safety function are built-in:

- The informative function is a 2D map (display on the device screen) which indicates the area where the energy is deposited and the total amount of energy delivered.
- The safety function is on the delivered power. Maximum output power and output fiber speed displacement are chosen by physician and delivered when footswitch is pressed and the output fiber speed displacement is over the pre-defined limit. If it the output fiber speed displacement is below the pre-defined limit then the delivered power is diminished.

The 2D map can be displayed only if the treatment surfaces are inclined less than 35 degree relative to the observation plane defined by the user. The user can divide the treated area in adjacent areas with an angle less than 35 degree or use the device without these optional functions.

The LipoControl includes the power supplies necessary to supply the laser and to ensure its temperature control using Peltier elements built on a ventilated radiator.

In addition, the LIPOCONTROL includes the whole of electronics and the functions allowing the parameter setting of the laser and the safe functioning of the device. The adjustments of the parameters are done using a LCD (Liquid Crystal Display) screen and a touch screen controlled by a PC.

5.3 Indications for use

LIPOCONTROL is indicated for: Laser assisted lipolysis.

LIPOCONTROL should be used to melt small amount of fat from small areas only such as chins or upper arms. LIPOCONTROL should not be used to melt larger volumes or areas of fat and on areas such as thighs, buttocks, or abdomen.

5.4 Performance data – Bench Test

LIPOCONTROL applications conform to Guidance on the content and organization of a premarket notification for a medical laser (June 1995) and to Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005).

Thus, LIPOCONTROL (with localization system) device conforms to safety and electromagnetic compliance standards:

- IEC 60601-1 (2005) – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-22 (2007) – Medical electrical equipment – Part 2-22: Particular requirements for the basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825-1 (2007) – Safety of laser products - Part 1: Equipment classification and requirements

- 21 CFR 1040.10 and 1040.11: Performance standards for light-emitting products_(lasers products and specific purpose laser products)
- IEC 60601-1-2 (2007) - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- FCC part 15 (2007)

Accuracy of the localization system has been checked in normal conditions and in worst case situations (influence of electrical noise and of magnetic distorsion); it is in good agreement with theoretical accuracy claimed by the supplier of the localization module.

Accuracy of the energy mapping display has been checked according to internal specifications. It complies with the mathematical model of projection in 2D plan of 3D data and to the energy pattern defined by OSYRIS MEDICAL.

Power regulation according to the speed displacement has been checked. When the speed is below the set value, the power is regulated linearly depending on the speed. When the speed is above the set value, the power set is delivered.

Verification of the stop of power delivery if the probe is outside the screen has been checked.

5.5 Performance data – Confirmatory Clinical Test

A feasibility study has been conducted on 4 subjects in order to demonstrate the feasibility and interest of using LIPOCONTROL with tracking system ability and energy mapping features on smaller treatment areas to melt small amount of fat.

Scope and duration:

In the study, 4 subjects were treated. 2 patients were treated on the chin, 2 patients on the upper arms using the Lipocontrol. 1 month follow up has been performed.

Measurements assessments:

Feasibility was assessed by validating that the investigator was able to define the ROI (region of interest) using the Lipocontrol, and by comparing the ROI recorded by the system to the one plotted on transparencies.

The interest of using Lipocontrol technology was assessed by reviewing the videos.

Safety and efficacy of the procedure were assessed using subjects questionnaires, and by evaluating side effects.

Results:

The results show that the Lipocontrol can be used on chin and upper arms. The treatment area can be flat or curved with up to 35 degree angle.

The results show the interest of the Lipocontrol:

- The tracking function and the power regulation associated with the canula tracking allow limiting the risk of accidental use of the laser, when the canula is not in the monitoring area.

- The power regulation allows having a better control of the energy delivery, avoiding excess of energy in a single point when canula is static, and regulating the power proportionally to the speed of the canula when the canula is moving, allowing a better homogeneity of the energy delivered, and a reduction of undesired local energy accumulation.

- The Lipocontrol allows applying a predefined value of energy per surface area, in each part of the tissue.

Safety and efficacy of the procedure were evaluated at 1 week follow up and at 1 month follow up:

- Subject recovery time was less than 1 week
- Minor and transitional pain or heat sensation was observed.
- No serious adverse event occurred during the study
- Minor and transitional side effects occurred during the study.
- On average, subjects are very satisfied with both the procedure and the clinical result.

➔ **Performance data based on bench tests and on clinical tests demonstrate the safety and effectiveness of LIPOCONTROL for its intended use.**

5.6 Substantial equivalence

LIPOCONTROL has the same intended use, design and function as predicate devices PHARAON LIPO manufactured by OSYRIS and cleared under K073617.

Summary preparation date: January 05, 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 21 2011

Osyris Medical
% Ms. Blandine Bouvet
Parc Scientifique de la Haute Borne
60 Avenue Halley
59650 Villeneuve D'Ascq, France

Re: K090754
Trade/Device Name: LipoControl
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ORK, GEX
Dated: January 11, 2011
Received: January 20, 2011

Dear Ms. Bouvet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

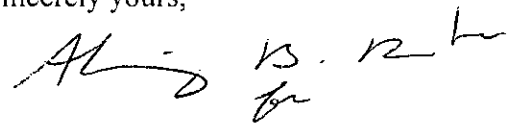
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OSTEOMED

INDICATIONS FOR USE

510(k) Number (if known): K090754

Device Name: **LIPOCONTROL**

Indications for Use:

LIPOCONTROL is indicated for:

Laser assisted lipolysis

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090754